

CLAIMS

What is claimed:

1. A test device for detecting an analyte suspected of being present in a liquid sample, comprising:

- 5 a. an absorbent sample applicator, for collecting the sample from a subject in need of testing for an analyte in a sample of a subject;
- b. a casing;
- c. a sample application well connected to said casing;
- d. a sample divider for dividing the sample into a first portion to be tested and a
10 second portion to be stored or used for optional confirmation testing; and
- e. a sample reservoir in fluid communication with said sample divider, for collecting said second portion of the sample for storage and optional confirmation testing.
2. The test device of claim 1, further comprising at least one test strip encased within said casing and in fluid communication with said sample divider, for enabling diagnostic testing
15 of said first portion of the sample.
3. The test device of claim 1, wherein said sample applicator further comprises an absorbent member and a handle.
4. The test device of claim 3, wherein said absorbent member further comprises a sponge.
5. The test device of claim 3, wherein said absorbent member further comprises a foam.
- 20 6. The test device of claim 3, wherein said absorbent member is treated with a solution that stimulates salivation in a subject from which the sample is collected.
7. The test device of claim 3, wherein said handle is substantially rigid and further comprises a textured grip for holding said sample applicator.

8. The test device of claim 2, wherein said casing further comprises a top portion and a bottom portion.

9. The test device of claim 8, wherein said top portion further comprises a reservoir attachment means.

5 10. The test device of claim 8, wherein said top portion further comprises a reservoir sealing means.

11. The test device of claim 10, wherein said reservoir sealing means is selected from the group consisting of foil, plastic, plastic coated foil, wax, and tape.

10 12. The test device of claim 8, said top portion further comprising a sample application well base.

13. The test device of claim 12, wherein said sample application well base further comprises said sample divider, said sample divider being in fluid communication with said reservoir and said at least one test strip.

15 14. The test device of claim 8, said top portion further comprising an aperture through which said as least one test strip can be observed, said aperture optionally having indicia to indicate the location of test results on said at least one test strip.

20 15. The test device of claim 8, said top portion further comprising an exterior surface and an interior surface and said bottom portion further comprises front, back, bottom and two side walls, each wall of said bottom portion having both an interior surface and an exterior surface.

16. The test device of claim 15, said at least one test strip being supported in a space defined by the interior surface of the top portion and the interior surfaces of the bottom portion.

17. The test device of claim 1, wherein said sample application well further comprises an expression means, for expressing the sample from said sample applicator upon said absorbent member being manually pressed into the expresser means.

18. The test device of claim 17, said expression means further comprising radial spokes against which the absorbent member is manually pressed and between which said sample flows to said sample divider.

19. The test device of claim 17, said expression means further comprising a wall against which said absorbent member is manually pressed and said wall having an aperture through which the sample flows to said sample divider.

20. The test device of claim 17, said expression means further comprising a wall against which said absorbent member is manually pressed and said wall having at least two apertures in fluid communication with said sample divider and through which said sample flows to said sample divider.

21. The test device of claim 1, said sample reservoir further comprising a reservoir aperture in fluid communication with said sample divider.

22. The test device of claim 21, said reservoir aperture further comprising an o-ring.

23. The test device of claim 1, said reservoir further comprising a reservoir rotation guide means.

24. The test device of claim 1, said reservoir being optionally removable.

25. The test device of claim 24, said reservoir further comprising a reservoir aperture cap.

26. The test device of claim 1, wherein the sample is a bodily fluid or derived from a tissue or a bodily fluid.

27. The test device of claim 1, wherein the sample is selected from the group consisting of blood, serum, plasma, urine, feces, spinal fluid, vaginal swabs, mucus, and tissue.

28. The test device of claim 1, wherein the analyte is an infectious agent or indicative of an infected state.

29. The test device of claim 1, wherein the analyte is an agent or substance indicative of a disease state.

5 30. The test device of claim 1, wherein said analyte of interest is selected from the group consisting of a drug, a drug of abuse, a hormone, a protein, a nucleic acid molecule, an etiological agent and a specific binding member.

31. The test device of claim 1, wherein the analyte is a drug of abuse.

32. The test device of claim 1, wherein the sample further comprises a biological sample.

10 33. The test device of claim 1, wherein the sample further comprises a viscous sample.

34. The test device of claim 1, wherein the sample further comprises oral fluid.

35. The test device of claim 1, wherein the sample further comprises saliva.

36. A method for detecting an analyte in a sample, comprising: contacting a test device of claim 1 with a sample and detecting the presence of said analyte in said sample.

15 37. A fluid specimen testing device comprising:

- a. a sample collection swab including an absorbent member and a handle;
 - b. a sample expression and division means, by which a first portion of the sample is expressed from the swab and divided into a second portion and a third portion;
 - c. a testing means in direct fluid communication with the second portion of the
- 20 sample, for testing the second portion of the sample for the presence of an analyte of interest; and

- d. a storage means in direct fluid communication with the third portion of the sample; for storing the third portion of the sample for later use, such as confirmation testing.

38. A saliva testing and storage device comprising:

- a. a fluid collection swab including a sponge portion adapted and suited to absorb an oral fluid specimen from the oral cavity of a test subject; and
- b. a testing cassette, including:
- c. an expresser means for expressing the specimen from the sponge portion upon the sponge portion being pressed into the expresser means;
- d. a specimen dividing means that divides the expressed specimen into a first portion and a second portion;
- e. a diagnostic testing means in direct fluid communication with the dividing mean that tests the first portion of the specimen;
- f. a storage means in direct fluid communication and into which the second portion of the specimen is collected and stored.

39. A method of detecting an analyte of interest in a sample of a subject, comprising:

- a. placing an absorbent collector in the subject's mouth and swabbing the subject's mouth until the absorbent collector is saturated with oral fluid or optionally saliva;
- b. placing the sample saturated absorbent collector in a sample application well of a test device containing a test strip for diagnostic purposes;
- c. manually pressing the saturated absorbent collector onto an expression means so that at least a portion of the liquid sample collected from the subject is expressed into the test device;

- d. waiting a period of time sufficient for the expressed liquid sample to flow into the device and be divided by the device into at least two portions, a first portion that is in fluid communication with the test strip and a second portion that is in fluid communication with a sample storage reservoir; waiting a period of time
5 sufficient for the first portion of the sample to be tested by the test strip for an analyte of interest, until the test is complete and then reading the results of the test; sealing the reservoir containing the second portion of the divided sample; and
- e. storing the second portion of the divided sample.

40. The method of claim 39, said step of sealing the reservoir containing the second portion of
10 the divided sample optionally further comprising the step of removing the reservoir from the test device.

41. The method of claim 39, wherein the analyte is an infectious agent or indicative of an infected state.

42. The method of claim 39, wherein the analyte is an agent or substance indicative of a disease
15 state.

43. The method of claim 39, wherein the analyte is a drug of abuse.

44. The method of claim 39, wherein the sample further comprises a biological sample.

45. The method of claim 39, wherein the sample further comprises a viscous sample.

46. The method of claim 39, wherein the sample further comprises oral fluid.

20 47. The method of claim 39, wherein the sample further comprises saliva.

48. A kit, comprising: at least one test device of claim 1 packaged together with instructions for use of said test device.